

IN THE CLAIMS:

Please amend claim 1 as follows:

(B1) ~~1. (Amended) A stable, liquid pharmaceutical formulation [comprising] consisting of interferon-beta, a stabilizing amount of a polyol ~~selected from the group consisting of mannitol, glycine and sucrose, [and]~~ a buffer capable of maintaining the pH of the formulation at a value between 3.0 and 4.0 and, optionally, albumin.~~

(2b) ~~C1~~

REMARKS

In order to expedite allowance of this application, the claims have been amended to specify that the formulation contains beta interferon, the buffer, mannitol, glycine or sucrose and optionally albumin. The use of the term "optionally" is appropriate and definite under the second paragraph of 35 U.S.C. § 112. See, e.g., Ex Parte Cordova, 10 U.S.P.Q.2d 1949 (B.P.A.I. 1988).

The amendment to the claims also eliminates the relevance (without conceding there was any) of the Hershenson and Cymbalista patents cited by the Examiner. Hershenson requires that either glycerol or polyethylene glycol be present in all instances. There is no teaching or suggestion that these materials can be eliminated and therefore their elimination is contraindicated. The Cymbalista patent relates to a method of stabilizing beta interferon in which a solution is admixed with known excipient and dialysed against an acetate buffer, filtered and then admixed with polyvinyl pyrrolidone. There is no teaching using a stabilizing amount of any of the excipients and, indeed, the PVP is indicated to function as a stabilizer in the table in column 2.

The Rideout patent has apparently been cited to teach sealing a pharmaceutical formulation in ampules or vials and therefore does not cure any deficiencies in the other references.

A combination of Cymbalista, Hershenson and Rideout would result in a material which always contains PVP as a stabilizer and at least one of glycerol or polyethylene glycol. This is not the claimed composition and the claimed composition is clearly novel and unobvious thereover.

In light of the foregoing amendments, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a notice of allowance is respectfully solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on July 30, 1997:

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Name of applicant, assignee or  
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Signature

July 30, 1997

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Date of Signature

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Respectfully submitted,

Edward A. Meilman

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